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10/084,545	02/25/2002	Sam L. Samuels	AD6799USNA	7978

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EXAMINER

AUGHENBAUGH, WALTER

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/084,545

Applicant(s)

SAMUELS ET AL.

Examiner

Walter B Aughenbaugh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 18-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 32-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/ŠB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 20, 2004 has been entered.

### ***Acknowledgement of Applicant's Amendments***

2. The amendments made in claims 1, 15, 17, 32 and 33 made in the Amendment filed February 20, 2004 (Amdt. C) have been received and considered by Examiner.
3. The amendments made in the abstract in Amdt. C have been received and considered by Examiner.

### ***Election/Restrictions***

4. On page 12 of Amdt. C, Applicant argues that the groups are "clearly linked" and that "the additional burden associated with the examination of claims 18 through 31 will not be serious", and therefore, the restriction requirement should be withdrawn. This is not found persuasive because, as previously stated in paragraph 3 of Paper 6, Group I (claims 1-17 and 32-34 and also claim 35 per the amendment made to claim 35 in Paper 5) is still nonetheless drawn to a balloon catheter cover and Group II (currently claims 18-31) is still nonetheless drawn to a process for making a tubular structure. As previously stated in paragraph 4 of Paper 4 and in paragraph 3 of Paper 6, because these inventions are distinct for the reasons given above and

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have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

As already stated in paragraph 3 of Paper 6, the requirement is still deemed proper and is therefore made FINAL.

***WITHDRAWN OBJECTIONS***

5. The objection to the abstract made of record in paragraph 15 of Paper 6 has been withdrawn due to Applicant's amendments to the abstract in Amdt. C.

***WITHDRAWN REJECTIONS***

6. The 35 U.S.C. 112 rejection of claim 15 that was repeated in paragraph 10 of Paper 6 has been withdrawn due to Applicant's amendments to claim 15 in Amdt. C.

7. The 35 U.S.C. 112 rejection of claim 33 made of record in paragraph 16 of Paper 6 has been withdrawn due to Applicant's amendments to claim 33 in Amdt. C.

8. The 35 U.S.C. 103(a) rejection of claim 33 over Cook in view of Fowler et al. and in further view of Killion et al. repeated in paragraph 14 of Paper 6 has been withdrawn due to Applicant's amendments to claim 33 in Amdt. C and has been replaced with the new 35 U.S.C. 103(a) rejection of claim 33 over Cook in view of Fowler et al. and in further view of Killion et al. that is made of record in this Office Action.

***REPEATED REJECTIONS***

9. The 35 U.S.C. 103(a) rejection of claims 1-9, 11-14 and 17 over Cook in view of Fowler et al. has been repeated for the reasons previously made of record in paragraph 11 of Paper 6 and for the following reasons that address the amendments made to the claims in Amdt. C: in regard to claim 1, the recitation "for covering the outer surface of a balloon catheter" is an intended use

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phrase that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987); furthermore, there is no teaching in Cook that precludes the tubular elastic fabric structure of Cook from covering the outer surface of a balloon catheter. In further regard to claim 1, the added recitation "wherein the tubular elastic structure is formed" does not affect the claimed structure, composition or properties. The amendment to claim 17 is clerical.

10. The 35 U.S.C. 103(a) rejection of claim 10 over Cook in view of Fowler et al. and in further view of Chaikof et al. has been repeated for the reasons previously made of record in paragraph 12 of Paper 6 and for the reasons provided above that address the amendments made to claim 1 in Amdt. C.

11. The 35 U.S.C. 103(a) rejection of claim 15 over Cook in view of Fowler et al. and in further view of Gilding et al. has been repeated for the reasons previously made of record in paragraph 13 of Paper 6 and for the reasons provided above that address the amendments made to claim 1 in Amdt. C. The amendments to claim 15 address the 35 U.S.C. 112 rejection of claim 15 repeated in paragraph 10 of Paper 6 and do affect the scope of the claim.

12. The 35 U.S.C. 103(a) rejection of claims 32 and 34 over Cook in view of Fowler et al. and in further view of Killion et al. has been repeated for the reasons previously made of record in paragraph 14 of Paper 6 and for the reasons provided above that address the amendments made to claim 1 in Amdt. C. The replacement of the term "sleeve" with --tubular elastic fabric

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structure-- in claim 32 does not affect the scope of the claim; the "sleeve" was interpreted by Examiner to be the tubular elastic fabric structure.

13. The 35 U.S.C. 103(a) rejection of claim 16 made of record in paragraph 17 of Paper 6 has been repeated for the reasons previously made of record in paragraph 17 of Paper 6 and for the reasons provided above that address the amendments made to claim 1 in Amdt. C.

14. The 35 U.S.C. 103(a) rejection of claim 35 made of record in paragraph 18 of Paper 6 has been repeated for the reasons previously made of record in paragraph 18 of Paper 6 and for the reasons provided above that address the amendments made to claim 1 in Amdt. C.

#### ***NEW REJECTIONS***

##### ***Claim Rejections - 35 USC § 103***

15. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Fowler et al. and in further view of Killion et al.

Cook, Fowler et al. and Killion et al. teach the balloon catheter cover as discussed in regard to claim 32 in paragraph 14 of Paper 6 and for the reasons provided above that address the amendments made to claim 1 in Amdt. C. Furthermore, Fowler et al. teach that the expansible fabric is braided (col. 5, line 30). Killion et al., however, teach that the expandable stent (of Killion et al.) achieves a variation in radial force along the length of the stent by varying stent strut dimensions such as width, length, spacing and overall size (col. 2, lines 66-col. 3, line 27 and Figures 1, 6 and 7). Therefore, one of ordinary skill in the art would have recognized to have varied the braiding yarn spacing along the length of the tubular elastic fabric structure taught by Cook and Fowler et al. as Killion et al. vary the strut spacing of the stent along the stent in order

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to provide a tubular elastic fabric structure with expansion properties that vary along the length of the tubular elastic fabric structure as taught by Killion et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the braiding yarn spacing along the length of the tubular elastic fabric structure taught by Cook and Fowler et al. as Killion et al. vary the strut spacing of the stent along the stent in order to provide a tubular elastic fabric structure with expansion properties that vary along the length of the tubular elastic fabric structure as taught by Killion et al.

Furthermore, the recitation "the varied properties along the length of the tubular elastic fabric structure are produced by varying the braiding yarn spacing along the length of the tubular elastic fabric structure" is a method limitation and therefore has been given little patentable weight since the method of forming the cover is not germane to the issue of patentability of the cover itself.

#### ***ANSWERS TO APPLICANT'S ARGUMENTS***

16. Applicant's arguments on pages 9-12 of Amdt. C regarding the 35 U.S.C. 103(a) rejection of claims 1-9, 11-14 and 17 over Cook in view of Fowler et al. have been fully considered but are not persuasive.

Applicant argues that "Cook does not describe a balloon catheter cover, but rather a reinforcing fabric that is internal to the balloon structure". As made of record in paragraph 12 of Paper 4 and in paragraph 19 of Paper 6, Cook teaches a balloon catheter cover comprising a tubular elastic fabric structure (item 23, Fig. 2) that covers the inner layer (item 22, Fig. 2) of the balloon (item 12, Fig. 2) (col. 2, lines 29-45). The phrase "balloon catheter cover" is interpreted by Examiner to recite a cover that is associated with a balloon catheter. The phrase "balloon

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catheter cover” does not positively recite any structural limitations that limit the cover to a cover that covers an entire balloon catheter. The tubular elastic fabric structure (item 23) of Cook is a balloon catheter cover because it covers the inner layer (item 22) of the balloon (item 12) as made of record in paragraph 12 of Paper 4 and in paragraph 19 of Paper 6. Applicant argues that Cook does not “teach or suggest elastic circumferential fibers and less elastic longitudinal fibers”, but this deficiency of Cook is taught by Fowler et al.; claim 1 is not rejected under 35 U.S.C. 102.

Applicant argues that “one seeking to improve the performance of balloon catheters that are commonly used in cardiac surgery would simply not consider the art of fluid dispensing containers to be reasonably pertinent” and therefore Cook and Fowler et al. cannot be combined since Fowler et al. is “drawn from a non-analogous art”, but Fowler et al. pertains to tubular elastic fabric structures, and Cook teaches a tubular elastic fabric structure (col. 2, lines 29-56 and col. 3, lines 10-22). One of ordinary skill in the art (i.e. the art of “balloon catheters that are commonly used in cardiac surgery”) would have recognized to have consulted Fowler et al. for a teaching that could be used to modify the tubular elastic fabric structure of Cook since Fowler et al. pertains to tubular elastic fabric structures. Cook and Fowler et al. are actually “drawn from” an analogous art in that both Cook and Fowler et al. pertain to tubular elastic fabric structures. Applicant argues that “the structural adaptations required to transform a fluid dispensing container liner into an operational balloon catheter would be more than trivial”, but the proposed combination of references does not propose a “transform[ation of] a fluid dispensing container liner into an operational balloon catheter”; Cook is the primary reference in the proposed



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combination of references, not Fowler et al. Furthermore, as stated in paragraph 19 of Paper 6 in response to Applicant's arguments presented in Paper 5:

Applicant argues that there is "no basis provided in the office action that would lead one skilled in the art of 'catheters' to look to 'fluid-dispensing containers' such as disclosed in Fowler et al. for modifying a compliant (elastic) 'balloon catheter'". Cook teaches a balloon catheter cover that comprises an elastic fabric structure that expands such that an increase in diameter does not require a decrease in length of the balloon and that the balloon (item 12), and therefore the cover (fabric structure, item 23), is of fixed length during expansion (col. 3, line 46-58). Therefore, one of ordinary skill in the art would have been amply motivated to consult Fowler et al., which also teaches a tubular elastic structure that has stretch and recovery capabilities in the circumferential direction while having no appreciable elongation at all in the longitudinal direction as made of record in paragraph 12 of Paper 4, in order to explore alternate fabric structures that achieve the effect of expansion of an elastic fabric tube in the circumferential direction while maintaining a fixed tube length as taught by Cook. The fabric taught by Fowler et al. is a fabric structure that achieves the effect of expansion of an elastic fabric tube in the circumferential direction while maintaining a fixed tube length that Cook achieves with the particular fabric taught by Cook. The fact that Fowler et al. teach a fluid-dispensing container is a matter of intended use; the fabric taught by Fowler et al. would readily be used by one of ordinary skill in the balloon catheter art since the fabric taught by Fowler et al. achieves exactly the same mechanical effects that are desired by those of ordinary skill in the balloon catheter art as taught by Cook as discussed above.

Applicant argues that there is no motivation to combine the references since "Cook requires that the elastomer and hard fibers be parallel to each other", but this is not the case; the condition that the elastomer and the hard fibers be parallel to each other is preferred as taught by Cook (see col. 3, lines 10-17). In response to Applicant's argument that there is no motivation to combine the references since the fabric of Cook is required to be a "loosely knitted 'loopy' structure", Cook teaches that the middle layer is "knitted loosely" during formation of the balloon, not that the middle layer in its final end product form is "knitted loosely" (see col. 3, lines 23-31 and 42-45). Applicant argues that there is no motivation to combine the references since the fabric of Cook is required to "be capable of expanding three-dimensionally", but Cook does not require that the balloon expands three-dimensionally; the condition that the balloon is "capable of expanding three-dimensionally" does not require that it expand three-dimensionally for the result described at col. 3, lines 46-55, especially lines 51-55. Furthermore, the fabric of

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Fowler et al. is capable of expanding three-dimensionally because Fowler et al. teach that when the longitudinal yarn is a non-stretch yarn, the tube expands radially but expands much less or not at all in the axial (i.e. longitudinal) direction (col. 4, lines 33-37). The requirements of Cook as alleged by Applicant are not requirements of Cook, and therefore, the references can be combined.

The recitation to which Applicant refers in the first paragraph of page 11 of Amdt. C is not a positive limitation, and there is no teaching in Cook that precludes the tubular elastic fabric structure of Cook from covering the outer surface of a balloon catheter.

Contrary to Applicant's arguments in the first paragraph of page 12 of Amdt. C, a *prima facie* case of obviousness has been established, and Applicant's arguments in Amdt. C that have been addressed above in this Office Action do not overcome the 35 U.S.C. 103(a) rejection of claims 1-9, 11-14 and 17.

17. Applicant's arguments in regard to the 35 U.S.C. 103(a) rejection of claims 2-17 and 32-35 in the third paragraph of page 11 of Amdt. C depend entirely on Applicant's arguments in regard to the rejection of claim 1 which have been addressed above in this Office Action and in paragraph 19 of Paper 6.

### ***Conclusion***

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. 4,834,755 to Silvestrini et al.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-

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1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh

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